

REMARKS

Claims 1-7, 11-14, and 16-21 are currently pending in this application, with claims 1-7 having been withdrawn from consideration in response to a previous restriction requirement. Claim 11 has been amended.

Telephone Interview

Applicants would like to thank the Examiner for the courtesies extended to Applicants' representative Lara Northrop during the telephone interview of January 5, 2010. During the Interview, removal of element (B) from the step of sandwiching in independent claim 11 was discussed and encouraged by the Examiner. Applicants have amended independent claim 11 consistent with the Examiner's suggestions.

Amendment to Claim 11

Applicants have amended claim 11 to recite, in relevant part, "the adhesion preventive layer being provided at an outermost surface of the first membrane, the first membrane covers the injured or deficient portion so that the biodegradable base layer faces the injured or deficient tissue". Basis for this amendment may be found, for example, in the specification on page 23, lines 18-21. Applicants have also amended claim 11 to remove element (B), i.e., "a tissue sandwiching part of an adhesion preventive membrane" from the step of sandwiching an injured or deficient tissue. As the step of sandwiching the injured or deficient tissue previously recited two alternatives, i.e., by step (A) OR step (B), the removal of element (B) restricts claim 11. Applicants assert that element (B) is patentable; however, Applicants have removed this element from independent claim 11 in an effort to advance prosecution of the present application. In view of the further narrowing of independent claim 11, Applicants submit that no additional search is needed as element (A) has already been searched and the present amendment does not broaden Applicants intended coverage. No new matter has been added.

Rejections Pursuant to 35 U.S.C. § 103(a)

Claims 11-14 and 16-21 have been rejected under 35 U.S.C. § 103(a) as being obvious over United States Patent Publication No. 2003/0114061 to Matsuda ("Matsuda") in view of United States Patent Publication No. 2004/0115241 to Calhoun ("Calhoun").

The Office Action alleges that Matsuda discloses adhesion preventative membranes comprised of a first membrane made of a collagen nonwoven fabric layer that provides membrane strength. The Office Action further contends that the biodegradable base layer may be laminated with a coating layer, containing a mixture of collagen and hyaluronic acid that prevents adhesion. However, the Office Action acknowledges that Matsuda fails to disclose sandwiching an injured tissue by two membranes or by a tissue-sandwiching portion of one membrane. To rectify this deficiency, the Office Action applies Calhoun as disclosing anti-adhesion membranes for use with implants to prevent post-surgical adhesions between the implant and the surrounding tissue. Calhoun discloses a method of reducing adhesions resulting from a surgical implant by covering all surfaces of an implant with a bioresorbable anti-adhesion membrane by sandwiching the implant within the membrane.

According to the Office Action, it would have been obvious to combine the membranes of Matsuda with the covering of an implant as disclosed in Calhoun. As recited on page 5 of the Office Action "[o]ne would have been motivated to do so since Matsuda does not disclose specific methods for the use of the disclosed membranes, but rather teaches that the inventive membranes can be used in known manners and in accordance with known methods."

Applicants have amended independent claim 11 to recite, in relevant part, the step of "sandwiching an injured or deficient portion of the injured or deficient tissue by a first membrane and a second membrane, so that the injured or deficient portion is not exposed and the portion is not in physical contact with the surrounding tissue". Applicants have removed element (B) which was previously provided in the alternative with the above-identified limitation. As such, Applicants' amended independent claim 11 requires that the sandwiching of the injured or deficient tissue occurs by both a first membrane and a second membrane. Accordingly, two separate membranes are required in Applicants' amended independent claim 11.

Applicants respectfully submit that neither Matsuda nor Calhoun discloses or suggests the use of two membranes to sandwich an injured or deficient tissue.

Although Matsuda discloses an adhesion preventive membrane formed by laminating a nonwoven fabric layer made of collagen fibers, and a coating layer containing a mixture of collagen and hyaluronic acid (*see* paragraph [0091] of Matsuda), Matsuda does not disclose applying a membrane, let alone two separate membranes on opposing sides of a tissue. In addition, Calhoun discloses wrapping, interweaving, blanketing, draping, taping, adjacent placement, juxtaposed positioning or sandwiching an implant with a single anti-adhesion membrane coating (*see* paragraph [0028] of Calhoun). Calhoun does not disclose applying two membranes on opposing sides of a tissue.

In addition, Applicants' claimed step of sandwiching an injured or deficient portion of the injured or deficient tissue by a first membrane and a second membrane, so that the injured or deficient portion is not exposed and the portion is not in physical contact with the surrounding tissue, is not obvious in view of the teachings of Matsuda, Calhoun or the combination of Matsuda and Calhoun.

Specifically, Matsuda discloses a collagen-containing adhesion preventive membrane that is used as a prosthetic membrane for membranous tissues (*see* paragraph [0001] of Matsuda). As acknowledged by the Examiner in the present Office Action on page 4 "Matsuda does not explicitly teach sandwiching an injured tissue by two membranes or by a tissue-sandwiching part of one membrane." Matsuda fails to disclose or suggest either the practice of sandwiching or the use of two membranes. Furthermore, Calhoun specifically describes the process in which the implant is wrapped with a single membrane prior to contacting the implant with the surrounding tissue (*see* paragraph [0027] of Calhoun). Further, Calhoun specifically describes in paragraphs [0026 – 0027]:

"due to the extreme thinness of the membrane 10, certain techniques, such as injection molding, may not be suitable, and may not provide sufficient performance. By using certain fabrication techniques, multiple layers of the polymeric materials may be formed in one membrane. Multilayer membranes may provide improved benefits and advantages especially when more than one resorbable material is used."

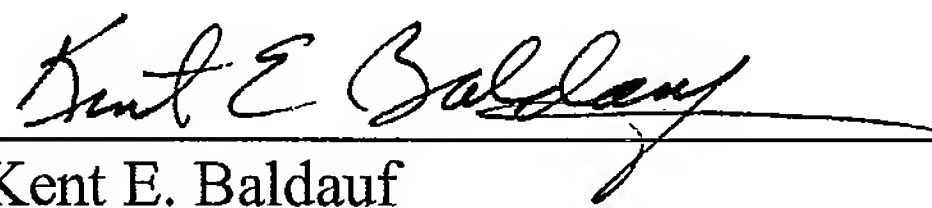
Accordingly, Calhoun specifically discloses that due to the required thinness, a single membrane may incorporate multiple layers. Calhoun in fact teaches away from the use of a first membrane and a separate second membrane.

Applicants respectfully submit that neither Matsuda nor Calhoun, nor the combination of Matsuda and Calhoun, discloses or suggests sandwiching an injured or deficient portion of the injured or deficient tissue by a first membrane and a second membrane, so that the injured or deficient portion is not exposed and the portion is not in physical contact with the surrounding tissue.

As discussed with the Examiner during the January 5, 2010 telephone interview, Applicants have further amended independent claim 11 to clarify that "the first membrane covers the injured or deficient portion so that the biodegradable base layer faces the injured or deficient tissue". Applicants submit that neither Matsuda nor Calhoun, nor the combination of Matsuda and Calhoun, discloses or suggests sandwiching an injured or deficient tissue by a first membrane and a second membrane wherein the first membrane covers the injured or deficient portion so that the biodegradable base layer faces the injured or deficient tissue.

Applicants respectfully traverse the rejection of claims 11-14 and 16-21 under 35 U.S.C. § 103(a). Applicants submit that claims 12-14 and 16-21 depend directly from independent claim 11 and are believed patentable for at least the reasons discussed above. Reconsideration of the rejections and allowance of pending claims 11-14 and 16-21 are respectfully requested.

Respectfully submitted,
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